

What is claimed is:

1. A micro-needle comprising:
an oblique structure comprising a base at a proximal end and a vertex, defining a vertex angle, at a distal end; and
an open lumen comprising a lumenal wall extending from said base to said distal end wherein said lumenal wall intersects said vertex at a point defining the apex of said micro-needle.
2. The micro-needle of claim 1, wherein said oblique structure defines a structural axis, said lumen defines a lumenal axis, and said structural axis intersects said lumenal axis at a point of axial intersection and at an intersection angle, wherein said point of axial intersection is at a point proximal to said apex and said intersection angle is less than half of said vertex angle.
3. The micro-needle of claim 2, wherein said axial intersection is at a point distal to said base.
4. The micro-needle of claim 2, wherein said axial intersection is at a point along said base.
5. The micro-needle of claim 2, wherein said axial intersection is at a point proximal to said base.
6. The micro-needle of claim 1, wherein said lumen has a diameter sufficient to exert a capillary force upon fluid present at said distal end.
7. The micro-needle of claim 6, wherein said lumen has a diameter in the range from about 10 to 200 microns.

8. The micro-needle of claim 7, wherein said lumen has a diameter in the range from about 70 to 150 microns.

9. The micro-needle of claim 1, wherein said oblique structure comprises a conical configuration.

10. The micro-needle of claim 1, wherein said oblique structure comprises a pyramidal configuration.

11. The micro-needle of claim 1, wherein said oblique structure comprises a molded plastic material.

12. The micro-needle of claim 1, wherein said luminal wall also intersects said oblique structure at a point diametrically opposite said apex, wherein the line between said apex and said point diametrically opposite said apex define an angled distal tip at said distal end.

13. The micro-needle of claim 12 wherein said distal tip is beveled.

14. A device for sampling biological fluid and measuring the concentration of at least one target constituent therein, comprising:

at least one micro-needle according to claim 1 wherein said at least one micro-needle configured for sampling biological fluid; and

a means for measuring a constituent contained within the sampled biological fluid, wherein said micro-needle is in fluid communication with said measurement means.

15. The device of claim 14, wherein said measurement means comprises an electrochemical cell.

16. The device of claim 14, wherein said biological fluid is interstitial fluid and said constituent is glucose.

¹⁷~~18~~. A system for sampling biological fluid from the skin of a patient and measuring a target analyte within the biological fluid, the system comprising:

at least one device according to claim 14;

a control means in communication with said at least one system, said control means comprising means for sending an input signal to said at least one device and for receiving an output signal from said at least one device, and

a software algorithm associated with said control means which automatically calculates and determines the concentration of the target analyte in the biological sample upon receipt of said output signal by said control means.

¹⁸~~19~~. The system of claim 18 wherein said at least one device comprises an array of micro-needles according to claim 14.

¹⁹~~20~~. A method for making the micro-needle of claim 1 comprising the steps of:
providing a mold comprising a cavity having configuration of the negative image of said oblique structure of the micro-needle of claim 1;

providing particulated material;

heating said particulated material until molten; and

transferring said molten material to within said cavity of said mold; and

cooling said molten material to provide a resulting oblique structure of the micro-needle of claim 1.

²⁰~~21~~. The method according to claim 20 wherein said step of providing a mold comprises the step of cutting the negative image of said oblique structure into said cavity.

21 ~~22~~. The method according to claim 21 wherein said step of cutting comprises using an electrical discharge machining electrode.

22 ~~23~~. The method according to claim 20 further comprising the step of providing a pin within said cavity for forming said micro-needle lumen.

23 ~~24~~. The method according to claim 20 wherein said particulated material comprises a plastic material.

24 ~~25~~. The method according to claim 20 wherein said method comprises plastic injection molding techniques.

25 ~~26~~. The method according to claim 20 wherein said method comprises powder injection molding techniques.

26 ~~27~~. A method for sampling a biological fluid from within the skin of a patient and for determining the concentration of a target analyte contained therein, the method comprising the steps of:

providing at least one micro-needle according to claim 1;
inserting said at least one micro-needle into the skin to a selected depth; and
transferring a sample of the biological fluid present at the open distal end of said lumen into an analyte measurement device.

27 ~~28~~. The method of Claim 27, wherein said step of transferring said sample comprises the step of exerting capillary force on the biological fluid present at the open distal end of said lumen.

28 ~~30~~. The method of claim 27 further comprising the step of determining the concentration of said target analyte within said sampled biological fluid.

29 31. The method of claim 30 wherein said biological fluid is interstitial fluid and said target analyte is glucose.

Claims 30-32
Class 264/228.1
30 32. A method of manufacturing a structure comprising the steps of:
providing a suitable material from which said structure can be fabricated by means of one or more micro-replication techniques;
fabricating said structure from said suitable material by means of one or more micro-replication techniques, wherein said structure has a proximal end defining a base and a distal end having a vertex wherein said base has a diameter in the range from about 100 to 2,000 μm and the line extending from the center of the base to the vertex defines a structural axis having a length in the range from about 100 to 10,000 μm ;
forming an open lumen within said structure, said open lumen extending from said base to said distal end, wherein the distal end of said open lumen intersects said vertex; and
customizing a tip at said vertex end, said customized tip being selectively angled for a particular application.

30 33. The method according to claim 32, wherein said open lumen during the step of fabricating.

32 34. The method according to claim 32, wherein said step of customizing comprises the use of an electrical discharge machining device.

33 35. The method according to claim 32 wherein said selectively angled tip comprises a beveled edge.

34 36. A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of an analyte within the sampled biological fluid, the kit comprising at least one micro-needle according to claim 1.

35 ~~40~~. A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of an analyte within the sampled biological fluid, the kit comprising at least one device according to claim 14.

36 ~~41~~. The kit of claim 40 wherein said at least one device comprises an array of micro-needles.

37 ~~42~~. A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of an analyte within the sampled biological fluid, the kit comprising at least one system according to claim 18.

38 ~~43~~. A device for delivering a formulation to across a biological barrier, comprising:
at least one micro-needle according to claim 1 configured to penetrate the biological barrier; and
a reservoir in fluid communication with said at least one micro-needle, wherein said reservoir is configured to contain a volume of formulation.

39 ~~44~~. A kit for delivering a formulation to across a biological barrier, the kit comprising at least one micro-needle according to claim 1.